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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/891,177 05/29/92 CHAIT

EXAMINER
B 18436

HENRY T. BURKE  
WYATT, GERBER, BURKE & BADIE  
645 MADISON AVE., 5TH FL.  
NEW YORK, NY 10022

18N1

ART UNIT	PAPER NUMBER
BROWN, G	

1805  
DATE MAILED:

04/16/93

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice re Patent Drawing, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, Form PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☒ NOTICE OF INFORMAL APPLICATION

Part II SUMMARY OF ACTION

- ☒ Claims 1-3 are pending in the application.  
Of the above, claims 1 and 2 are withdrawn from consideration.
- ☐ Claims \_\_\_\_\_ have been cancelled.
- ☐ Claims \_\_\_\_\_ are allowed.
- ☒ Claims 3 are rejected.
- ☐ Claims \_\_\_\_\_ are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
- ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved. ☐ disapproved (see explanation).
- ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to a process for the sequence analysis of polypeptides, classified in Class 436, subclass 89.

II. Claim 3, drawn to a method of generating an amino acid sequence by *in vitro* translation, classified in Class 435, subclass 68.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct processes which have acquired a separate status in the art as shown by their different classification.

Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

During a telephone conversation with Henry Burke on 3/9/93 a provisional election was made with traverse to prosecute the invention of group II, claim 3. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1 and 2 withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The application contains several drawing Figures (e.g. Figure 1, of example 1) in the specification. Applicants are also advised that several Figures were given page numbers. Since drawings are left separate from the specification there are now gaps in the pagination. All drawings should be removed from the specification and presented as formal drawings and the specification re-paginated.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 3 is rejected under 35 U.S.C. 103 as being unpatentable over Noren et al. (Noren) in view of Stryer and Watson et al. (Watson).

Noren teaches a method of producing large quantities of a polypeptide by methods of *in vitro* transcription and translation.

Noren does not teach inhibition of translation to produce polypeptides of varying lengths.

Stryer teaches that puromycin can be enzymatically added to the carboxyl end of a growing peptide chain during translation of mRNA. This addition inhibits further peptide chain elongation; the synthesized peptide chain having the attached puromycin residue then dissociates from the ribosome.

Watson teaches methods of DNA sequencing that involves *in vitro* synthesis of DNA molecules and chain termination techniques to create DNA molecules of all possible lengths suitable for sequencing.

It would have been obvious to one of ordinary skill in the art to use puromycin in the *in vitro* translation methods taught by Noren, as a method to generate a nested set of polypeptides that vary in length and represent all possible lengths. The collection of polypeptides would naturally represent a complete collection of all lengths because puromycin (depending upon the concentration of the antibiotic added to the *in vitro* translation reaction) would randomly be incorporated into the growing polypeptide chain and stop further elongation. Therefore a nested set of polypeptides would be generated that could be used for sequence analysis. This is basically the same methodology as taught by Watson for generating DNA fragments varying in length useful in DNA sequence analysis. For example Watson teaches that in DNA sequencing a nested set of DNA molecules is generated *in vitro* by DNA polymerization and chain termination techniques. All possible chain lengths can be generated and can be used for sequence analysis. The applicants have simply applied this methodology to generating polypeptides of all possible lengths by combining the known methods of *in vitro* translation and the known chain termination action of puromycin. Motivation to do so can be found in the art recognized fact that there is a need for rapid, efficient and accurate polypeptide sequence analysis. This

Art Unit 1805

method would generate large quantities of polypeptides suitable for said polypeptide sequence analysis.

Therefore absent unexpected results the invention of the instant application would have been prima facie obvious.

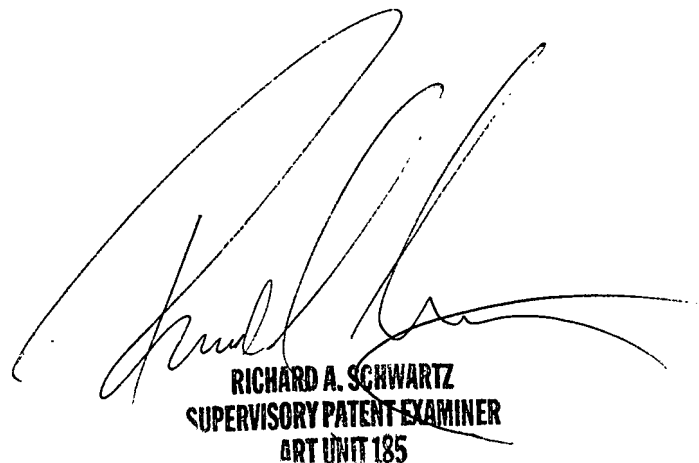
Claim 3 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The inventive process steps have been omitted from this method claim and claim language is confusing in the recitation of "derived from a single polypeptide chain." If *in vitro* translation is used in the method to generate a collection of all possible length peptides, then said peptides are derived from mRNA not a single polypeptide chain.

Applicants are advised that several Figures were given page numbers. Since drawings are ~~kept~~ separate from the specification there are now gaps in the pagination. All drawings should be removed from the specification and the specification re-paginated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Gary L. Brown whose telephone number is (703) 308- 4761. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Gary L. Brown Ph.D

Art Unit 1805



**RICHARD A. SCHWARTZ**  
**SUPERVISORY PATENT EXAMINER**  
**ART UNIT 185**



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY DOCKET NO./TITLE
07/891,177	05/29/92	CHAIT	B 18436

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DATE MAILED: 04/16/93

**NOTICE OF INFORMAL APPLICATION**

(Attachment to Office Action)

This application does not conform with the rules governing applications for the reason(s) checked below. The period within which to correct these requirements and avoid abandonment is set in the accompanying Office action.

A. A new oath or declaration, identifying this application by the application number and filing date is required. The oath or declaration does not comply with 37 CFR 1.63 in that it:

1. ☐ does not identify the city and state or foreign country of residence of each inventor.
2. ☐ does not identify the citizenship of each inventor.
3. ☐ does not state whether the inventor is a sole or joint inventor.
4. ☐ does not state that the person making the oath or declaration:
  - a. ☐ has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
  - b. ☐ believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.
  - c. ☐ acknowledges the duty to disclose information which is material to the examination of the application in accordance with 37 CFR 1.56(a).
5. ☐ does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application serial number, country, day, month, and year of its filing.
6. ☐ does not state that the person making the oath or declaration acknowledges the duty to disclose material information as defined in 37 CFR 1.56(a) which occurred between the filing date of the prior application and filing date of the continuation-in-part application which discloses and claims subject matter in addition to that disclosed in the prior application (37 CFR 1.63(d)).
7. ☐ does not include the date of execution.
8. ☐ does not use permanent ink, or its equivalent in quality, as required under 37 CFR 1.52(a).
9. ☐ contains non-initialed alterations (See 37 CFR 1.52(c)).
10. ☐ Other:

B. Applicant is required to provide:

1. ☐ A statement signed by applicant giving his or her complete name. A full name must include at least one given name without abbreviation as required by 37 CFR 1.41(a).
2. ☐ Proof of authority of the legal representative under 37 CFR 1.44.
3. ☐ An abstract in compliance with 37 CFR 1.72(b).
4. ☐ A statement signed by applicant giving his or her complete post office address (37 CFR 1.33(a)).
5. ☐ A copy of the specification written, typed, or printed in permanent ink, or its equivalent in quality as required by 37 CFR 1.52(a).
6. ☒ Other: *The Pages Are Misnumbered*